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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------------|
| 09/834,700 | 04/12/2001 | Andreas Braun | 24736-2035 | 5035 |
| 24961 | 7590 | 01/10/2003 | | |
| HELLER EHRMAN WHITE & MCAULIFFE LLP 4350 LA JOLLA VILLAGE DRIVE 7TH FLOOR SAN DIEGO, CA 92122-1246 | | | EXAMINER | GOLDBERG, JEANINE ANNE |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1634 | |

DATE MAILED: 01/10/2003

(C)

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------------|---------------------------------------|---------------------------------------|
| Office Action Summary | Application No. 09/834,700 | Applicant(s) BRAUN, ANDREAS |
| | Examiner Jeanine A Goldberg | Art Unit 1634 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE one MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 20 November 2002.

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-75 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) _____ is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) 1-75 are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
 If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

| | |
|---|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____. . | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

1. This action is in response to the papers filed November 20, 2002. Currently, claims 1-75 are pending.
2. It is noted that the response did not elect a group for prosecution. The restriction requirement set forth on June 21, 2002 has been reconsidered and the modified restriction requirement appears below.

Election/Restrictions

3. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-8, 11-20, 44-53, 69-71, 75, drawn to nucleic acids, probes, primers, vectors, cells, kits and methods of producing a polypeptide by culturing cells, classified in class 536, subclass 23.1, 24.31, 24.33, 435/320.1, 325, for example.
 - II. Claims 9-10, 54, drawn to polypeptides, classified in class 530, subclass 350.
 - III. Claims 21-43, 61-68, drawn to methods of detecting nucleic acid variants, classified in class 435, subclass 6.
 - IV. Claims 55-56, drawn to transgenic animals, classified in class 800, subclass 8.
 - V. Claims 57-60, drawn to methods of identifying molecules that modulate biological activity of AKAP10 protein, classified in class 424, subclass 9.2.
 - VI. Claims 72-74, drawn to an anti-AKAP10 ribozyme, classified in class 536, subclass 24.5.

4. The inventions are distinct, each from the other because of the following reasons:

A) The inventions of Groups I, II, VI and IV are patentably distinct because they are drawn to different products having different structures and functions. The nucleic acid of Group I is composed of nucleotides linked in phosphodiester bonds and arranged in space as a double helix. The polypeptide of Group II is composed of amino acids linked in peptide bonds and arranged spatially in a number of different tertiary structures including alpha helices, beta-pleated sheets, and hydrophobic loops (transmembrane domain). The anti-AKAP10 ribozyme of Group VI has UG at the 5' end of the substrate binding. The transgenic animal of Group IV is a composition made up of structurally and functionally complex biological systems. Furthermore, the products of Groups I, II, and IV can be used in materially different processes, for example, the DNA of Group I can be used in hybridization assays, the polypeptide of Group II can be used to make fusion protein with an enzymatic function, while transgenic animals can be used to express different proteins other than AKAP10 variant protein. Consequently, the reagents, reaction conditions, and reaction parameters required to make or use each invention are different. Therefore, the inventions of Groups I, II, VI and IV are patentably distinct from each other.

B) Group (II, IV, VI) and (III, V) are patentable distinct inventions because the protein, transgenic animals and anti-AKAP10 rybozyme of Group II, IV and VI is not relied upon in the method of Group III and V. Instead Group III and V uses nucleic acids. Therefore, the inventions are novel and unobvious over one another.

C) The inventions of Group III and V are patentably distinct methods because they each have different objectives, different uses, different reagents and different method steps. The method of Group III is for detecting variants of nucleic acids and for detecting increased susceptibility to morbidity or predisposition for premature or increased or early mortality. Alternatively, the method of Group V is for identifying molecules that modulate the biological activity of AKAP10 protein. Therefore the methods are distinct over one another.

D) Inventions I and (III and V) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the nucleic acids of Group I may be used in materially different methods as exemplified by the numerous different methods claimed. Moreover, the nucleic acids may be used in purification methods, aptamer screening methods, hybridization assays, and antisense methods.

5. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by the different classifications and their divergent subject matter, restriction for examination purposes as indicated is proper.

Art Unit: 1634

6. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jeanine Goldberg whose telephone number is (703) 306-5817. The examiner can normally be reached Monday-Friday from 8:00 a.m. to 5:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152. The fax number for this Group is (703) 305-3014.

Any inquiry of a general nature should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Jeanine Goldberg
December 31, 2002


W. Gary Jones
Supervisory Patent Examiner
Technology Center 1600